URINARY TRACT INFECTION DIAGNOSIS AND RESPONSE TO THERAPY IN LONG-TERM CARE FACILITIES: A PROSPECTIVE, OBSERVATIONAL STUDY

by

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A Thesis submitted to the

School of Graduate Studies

in partial fulfillment of the requirements for the degree of

Master of Science in Medicine

Clinical Epidemiology

Memorial University of Newfoundland

October 2017

St. John's Newfoundland and Labrador

ABSTRACT

Background: Urinary tract infection (UTI) is common, often over-diagnosed, in long-term care (LTC) facilities and a source of inappropriate antibiotic prescription.

Objectives: (1) Establish factors associated with a nurse's decision to send a urine culture (UC), and if those factors were associated with a positive culture result; (2) to determine if antimicrobial therapy is associated with functional improvement.

Method(s): 101 LTC residents were prospectively identified and assessed after submission of a urine specimen for culture. Logistic regression was performed to identify variables associated with a positive culture result.

Result(s): Change in behaviour, dysuria, and change in character of urine were the three main reasons for UC collection. Male sex and change in mental status were the only significant predictors of culture positivity. Treatment did not lead to significant improvement in ADL score.

Conclusion: UCs obtained from LTC residents is often not appropriate and antibiotic treatment of residents from whom urine specimens are obtained does not lead to functional improvement.

ACKNOWLEDGEMENTS

Peter Daley, for motivation and unwavering support

Microbiology Laboratory at the Health Sciences Centre, for their patience and support

My family for their support and encouragement

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Abbreviations

LTC(F)	Long-term care (Facility)
UTI	Urinary Tract Infection
GU	Genitourinary
ASB	Asymptomatic Bacteriuria
ASP	Antimicrobial Stewardship Program

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Chapter 1: Introduction

1.1 Urinary Tract Infection

The urinary system can be categorized into an upper tract and a lower tract. The upper portion of the urinary tract includes the kidneys and the ureters, while the lower portion, contained in the pelvis, include the terminal parts of the ureters, the bladder and the proximal part of the urethra. UTI is a microbial infection occurring in any part of the urinary tract (1); lower tract infections include urethritis (i.e., inflammation or infection of the urethra), cystitis (i.e., bladder infection) and, in men, prostatitis (i.e., acute or chronic infection of the prostate gland)(2). Upper tract infection is commonly referred to as pyelonephritis or kidney infection (1, 2).

UTIs can be further classified as uncomplicated or complicated (based on normal or abnormal underlying anatomy) and may be symptomatic but often they are not (2, 3). UTIs, while sounding simple, are hard to define (especially in elderly populations) and a concise definition of UTI and its associated symptoms does not exist; however, there are consensus guidelines that provide conserved criteria that are often used in diagnosis (4). The presence of bacteria in urine culture without symptoms is defined as asymptomatic bacteriuria (ASB).

1.2 Risk Factors

The elderly population (especially those in the long-term care [LTC] setting) are at an increased risk for developing many types of infections and will experience an increased morbidity associated with these infections (3). This predisposition to acquiring infections can be partly explained by age-related immune system changes, chronic disease(s), and

overall physical disability. In the LTC setting, additional factors such as closed environment (which favors a constant exposure to microorganisms) with frequent contact to personnel and other residents, and limited ventilation and filtration/removal of recirculated air (3) may also contribute.

One of the most common infections in the elderly population (and the LTC population) are urinary tract infections (UTIs), accounting for 30-40% of all infections (5). The increased prevalence of UTI in the elderly can be attributed to age-related changes in the urinary tract including anatomic changes and/or altered physiology; but there are, however, other proposed risk factors including genetic and behavioural factors that increase the likelihood of acquiring UTI (3, 4). Additionally, comorbid conditions including diabetes, dementia and incontinence have all been described as independent risk factors for UTI (5).

1.3 Clinical Presentation

In the elderly, the symptoms associated with UTI are often highly variable and nonspecific (i.e., are not localized to the genitourinary tract)(4). Symptoms can be especially difficult to assess in those with diminished communication abilities and/or with poor baseline function (as is seen in the institutionalized elderly population)(4, 6).

Symptomatic infection, when it occurs, can present as acute lower-tract symptoms such as increased frequency (i.e., need to urinate more frequently), dysuria (i.e., burning upon urination), increased urgency, new onset or worsening incontinence or suprapubic discomfort (3, 7). Upper tract UTI presents with systemic symptoms such as fever and

costovertebral angle tenderness (i.e., back pain) or gross hematuria (i.e., blood in the urine) (3).

Many physicians will believe that lethargy, confusion, change in mental status or an overall change in baseline function are associated with UTI, but these symptoms are not specific to UTI and can be difficult to assess in those with impaired cognition or chronic and/or extensive comorbidities (e.g., diabetes)(4). If such changes occur, other avenues such as recent medication changes should be evaluated before testing for UTI (8). Similarly, foul-smelling urine is often attributed to UTI but this may be due in part to other issues like dehydration (3, 9). A recent prospective observational cohort study found that the presence of malodorous urine and urine turbidity did not increase the likelihood of having a UTI nor did its absence decrease the likelihood of having a UTI – thus, these urine characteristics have no clinical utility in the evaluation of a potential UTI and should not be used as clinical indicators (10). Using smell and/or turbidity only increases the risk of patients being inappropriately treated with antimicrobials.

1.4 Diagnosis

Clinical diagnosis of UTI is difficult in the elderly population (3). Many elderly have chronic symptoms associated with comorbid disease and have difficulty in communication, which may interfere with clinical assessment (3, 11). Furthermore, other chronic genitourinary symptoms like chronic incontinence are not associated with UTI, even though most individuals with these symptoms will have a positive urine culture (3). Twenty-five to fifty percent of institutionalized elderly have a positive urine culture at any given time, so residents with symptoms from any source will have a high probability

of a concurrent positive urine culture (3, 9). Only approximately 10% of episodes of fever without localizing symptoms in residents without an indwelling catheter will have a urinary source (3).

When a physician suspects UTI, the minimum laboratory evaluation for UTI should include urinalysis (i.e., microscopic evaluation of the urine components) and urinary dipstick to evaluate for the presence of leukocyte esterase and nitrites (i.e., bacterial metabolites) (5). In fact, dipstick testing can be used effectively to rule out UTI if it is negative for leukocytes esterase and nitrites since it has been shown that the negative predictive value for such components is close to 100% (12).

Other laboratory investigations for evaluation of UTI may include a urine culture. Urine culture is a diagnostic test in which collected urine is incubated on culture media and bacteria are identified. Urine culture will determine how many bacteria are present in the sample; this should be collected prior to initiation of antimicrobial therapy. If bacteria are present (i.e., the urine culture is *positive* representing significant growth), this signifies bacteriuria (i.e., bacteria in the urine) and can be quantitatively represented by reporting the number of bacteria colony-forming units per litre (CFUs/L). The threshold for reporting a urine culture as positive may vary, but is often reported as 10^6 CFUs/L, according to the Clinic and Laboratory Standards Institutes published guidelines. If no bacteria are present or there are not enough bacteria present, the culture will be reported as negative, signifying non-significant growth.

A positive urine culture is not sufficient to diagnose a UTI but it is required for the microbiologic diagnosis (3). That is, a positive urine culture will provide the

identification of the bacteria (or yeast) as well as provide antimicrobial susceptibility to aid in treatment decisions. A negative urine culture, however, will exclude the possibility of a urinary tract infection (3).

Unfortunately, however, there are significant problems that are frequently encountered in the collection, testing and interpretation of urine samples (4). Ideally, a urine specimen should be collected with mid-stream urine via the clean-catch method. If this not possible, such as in cases where controlled voiding is impossible or in highly functionally impaired patients, an in-and-out catheterization should be performed to collect the sample. This methodology is to minimize bacterial contamination of the specimen by normal genitourinary flora (especially in females) that will increase the likelihood of having a false-positive culture or lead to misinterpretation of normal flora as pathogenic (leading to inappropriate antimicrobial treatment) (3, 4). Furthermore, in those residents with a chronic indwelling catheter, the existing catheter should be removed and a new catheter inserted prior to obtaining the urine sample. Bacterial biofilms form on the interior surface of the catheter and as a result, culture collected in this way do not represent the actual bladder microbiology (4). Unfortunately, adherence to ideal collection methods may be inadequate as shown by Pallin et al. (2014) in the acute-care setting (which is not often different than the LTC setting) (4, 13).

1.5 The Issue of Over-Diagnosis

The most common bacterial infection diagnosed among residents in LTC setting is UTI (11). While diagnosis of UTI is common in LTC, it is often incorrectly diagnosed (14). LTC residents have a high prevalence of asymptomatic bacteriuria (ASB) which

contributes to over-diagnosis of UTI (15). Physicians must decide if a resident's clinical decline is due to UTI or some other etiology. UTI can present with a continuum of signs and symptoms from localized genitourinary (GU) symptoms such as dysuria, to bacteremia, resulting in septic shock (11). The elderly, however, may present with atypical or non-localizing symptoms which are hard to discern because many residents in LTC have severe chronic comorbidities such as diabetes and heart failure or may have chronic GU symptoms from additional comorbid illnesses which clouds the identification of new or worsening symptoms (5, 11).

While published diagnostic guidelines for UTI in LTC exist, they have never been clinically validated (16) nor updated since their publication in the early 1990s (17). There is low adherence to these guidelines among physicians, since guidelines require that treatment be limited to residents with localized GU symptoms (18). As a result, when a resident is showing signs of clinical alteration or decline, a common practice is to send a urine specimen for culture . Urine culture, when positive, may not be useful in establishing a diagnosis of UTI given the high prevalence of ASB in this population (14).

Many of the signs and symptoms identified by nurses, physicians, or family as UTI are not attributable to UTI at all (19). Practitioners surveyed have suggested that factors such as a change in the character of urine (colour, turbidity, and odour), change in mental status or increased falls are associated in the LTC setting with UTI (20), but evidence does not support this (21, 22). Generalized non-specific symptoms may be caused by concurrent illnesses. For example, a change in the character of urine can be

caused by dehydration or diet (9, 19) and a change in mental status can be caused by other infections, dehydration or an adverse effect from new medication (9).

1.6 Asymptomatic Bacteriuria (ASB)

Confounding the usefulness of urine culture in LTC is the high prevalence of ASB. Twenty-five to fifty percent of women and 15-40% of men in LTC without an indwelling catheter have ASB (11). ASB is associated with increased functional impairments, bladder and bowel incontinence, and cognitive impairment (9). The main contributing factor to the prevalence of ASB is likely voiding abnormalities that are often associated with neurological disease such as cerebrovascular disease, Parkinson's and Alzheimer's disease (11), of which many LTC residents are afflicted.

ASB is defined as the presence of bacteria or yeast in the urine ($>10^6$ colony-forming units/litre) in the absence of any urinary specific symptoms (6, 19). Prevalence of ASB is highest in LTC residents with severe functional impairment, and treatment of ASB is not associated with a decrease in rate of symptomatic infection or survival (5, 9, 15, 23, 24). Despite this, ASB accounts for one-third of prescriptions for suspected UTI, with one study finding that half of antibiotics prescribed for suspected UTI were administered to ASB patients (25, 26).

There is no evidence that treatment for ASB is beneficial, since treatment does not reduce the prevalence of bacteriuria, frequency of symptomatic UTI or mortality (14, 25). In fact, re-infection or development of symptomatic UTI is more likely to occur early post-treatment (11). Treatment of ASB may be harmful, as it can lead to the emergence of

multi-drug resistant organisms (MDROs), increase adverse drug events and increase rates of *Clostridium difficile* associated diarrhea (CDAD) (19, 25, 27). In a study of nursing homes in Rhode Island, residents with ASB treated with antibiotics were 8.5 times more likely to develop CDAD within three months following treatment (28).

1.7 Difficulty with Ascertaining Signs and Symptoms

Residents with cognitive impairment or decline are more likely to have a positive urine culture than residents without cognitive impairment (15). Residents with baseline cognitive dysfunction frequently experience further cognitive deterioration with any change in status (19). Therefore, a LTC resident identified as having changes in mental status will often have bacteriuria (positive urine culture), which leads to inappropriate antibiotics being prescribed in residents with ASB (19). If the resident's condition improves, irrespective of whether this is attributed to the antibiotic therapy, physicians and nurses may be more likely to initiate antibiotic treatment in the future for such non-localized symptoms (9), especially in the absence of validated diagnostic criteria.

When a resident presents with diffuse, non-specific symptoms such as restlessness, fatigue, or not "being themselves" (21) it is hard to distinguish between UTI and ASB. Physicians often manage LTC patients by telephone using nurse's reports of clinical findings, rather than examining the resident (9), and nurses often order urine cultures based on their own assessment (29). As a result, when a positive urine culture is received an antibiotic may be inappropriately prescribed due to inadequate communication between physicians and nurses. (29). Similarly, with receipt of a positive urine culture, a physician when deciding to prescribe antibiotics, must assess the short-

term (i.e., failure to treat an emerging infection) and long term risks (i.e., contributing to antimicrobial resistant organisms); typically in this situation, the short term risks are perceived to outweigh the long-term risks (25). These factors may contribute to over-diagnosis and overtreatment of UTI.

1.8 Solutions to curb the issue of over-prescribing and over-diagnosis

Usually, LTC settings may not have the benefit of a local antimicrobial stewardship program (ASP) as hospitals have. ASP is the practice of using the correct antibiotic, at the optimal dose, duration and frequency to cure an infection, while minimizing risks to the patient and limiting the development of antimicrobial resistance (9). Currently, there is no standardization of stewardship components, implementation strategies or evaluation for LTC (30), but ideally a stewardship intervention would focus on standardizing indications for initiation of treatment for UTIs, limiting the chronic or prophylactic use of antimicrobials, and promoting short-course therapy for bacterial infections (31). Implementation of an ASP can reduce drug costs, antimicrobial resistance and rates of nosocomial infections (31, 32).

Multifaceted interventions like clinical algorithms targeting nurses and physicians have been shown to reduce the rate of antibiotic prescription for urinary indications (39% prior to intervention versus 28% following intervention, weighted mean difference -9.6%, -16.9% to -2.4%)(26). Interventions such as the one employed by Standford Place Care Campus on Vancouver Island, Canada included a self-learning package on ASB and UTIs combined with a clinical pathway for diagnosis and management of UTIs; they found an

improvement in communication between nurses and physicians, improved clinical diagnosis and a 36% reduction in antibiotic-treated UTIs (29).

Before an ASP can be implemented, it is pertinent to know the local habits with regards to diagnosis and treatment of UTIs in LTC facilities. We performed a prospective, observational study to determine the reason(s) that nurses in LTC were ordering urine cultures, and if these reasons for collection were associated with a positive urine culture. Similarly, we wanted to examine if physicians were making decisions consistent with published guidelines [McGeer criteria(17)] for diagnosis of UTI in residents without an indwelling catheter. At the time of the study, physicians and staff were not following any type of local guideline. We also assessed the clinical response of a resident to therapy by measuring their functionality prior to treatment, during treatment and following treatment. To date, no other study has examined clinical outcomes following therapy for UTI in LTC.

1.9 Thesis Objectives

The primary objectives of this study were:

1. Identify the reasons associated with a nurse's decision to send a urine sample for culture
2. Identify the symptoms associated with positive urine culture
3. Assess clinical response to antibiotic therapy by measuring the patient's functional ability and initial symptoms and continuing to monitor their status by

reassessing the patient at 48-hours and 5-7 days following treatment initiation for all included patients.

The secondary objectives(s) were:

1. To determine if a physician's decision to treat the suspected UTI with antibiotics complied with the culture and sensitivity reports released by the microbiology laboratory
2. To determine if treatment decisions followed published guidelines (17) for diagnosis of UTI in patients without an indwelling catheter.

The role of Carla Penney in this study was data collection and performing data analysis. (ethics, manuscript publication, study design).

Chapter 2: Methods

2.1 Study Design

The study was a prospective, observational cohort examining the behaviour of LTC nursing staff who submitted a urine culture specimen from a resident specimen. The nurse (or delegate) who collected the specimen was identified and interviewed at several time points, including the day the urine specimen was submitted to the microbiology laboratory for culture, and 48-hours and five to seven days following urine culture submission. Therefore, the study prospectively enrolled specimens but retrospectively examined the behaviours of nurses. The study was approved by Health Research Ethics Authority, who granted permission for research staff to approach nursing staff to collect relevant data. Information sheets on the study and consent forms were circulated to all participating LTC facilities prior to initiation of the study. A sample size calculation was not performed but determined based on feasibility; a sample size of 100 specimens was chosen.

2.2 Setting and Participants

Six LTC facilities (LTCF) (Agnes Pratt, Glenbrook Lodge, former Hoyles-Escasoni, St. Patrick's Mercy, Saint Luke's and Masonic Park) located in the metro-region of St. John's, Newfoundland, were selected for inclusion in the study based on their high urine culture submission rates. These facilities range from 40 to 377 patient beds with most facilities providing level three and level four care to residents (i.e., those who require moderate to total assistance with daily functioning).

Participants were identified based on receipt of a urine specimen from one of the participating LTCF by using the search function in the MEDTECH EHR system. Following identification, a researcher (CP) visited the relevant LTCF to determine further patient eligibility by interviewing the nurse (or delegate if the nurse was unavailable) who collected and submitted the urine. Receipt of a urine in the microbiology laboratory was considered sufficient evidence that the submitting nurse suspected a UTI.

Participants were not included in the study if they were not anticipated to remain in the LTCF (e.g., short-term resident or pending discharge); had an anticipated life expectancy of less than four weeks as assessed by nursing staff; were less than 65 years of age; had an indwelling catheter or other surgical urinary collection device; were currently on renal dialysis; were receiving antimicrobials for any indication or if they had resided in the LTCF for less than four weeks (staff are unable to determine resident's baseline functional status).

2.3 Data Collection

Between June 24 and July 17, 2013 and between January 20 and March 20, 2014, consecutive urine samples received in the clinical microbiology laboratory from the LTCF were identified. Once at the LTCF, the researcher identified the nurse who collected the urine to request the reason(s) for the urine submission. The nurse (or delegate) was interviewed at three time points to collect patient information including comorbidities, baseline functional capacity (28-point score of activities of daily living (long- form ADL) scale (RAI-MDS 2.0)(33) including mobility in bed, transfers, locomotion, dressing, toileting, personal hygiene and feeding, and a four-point mental

status care). This scale was completed at the time of the initial interview by the researcher asking the nurse (or delegate) which activities required assistance by the resident at that time and to what degree, with the researcher tallying the final score; the same procedure was followed for determining the resident's current mental status. The patient, the patient's caregivers, the patient's family and the attending physician were not interviewed.

2.4 Main Study Outcome

Urine culture was performed quantitatively, according to laboratory protocol and reported according to CSLI guidelines (34). A positive urine culture result was defined as a growth of at least 10^6 colony-forming units/liter of uropathogenic bacteria.

2.4.1 Baseline Variables Assessed

Study variable(s) considered to be possibly associated with significant growth in urine culture were selected based on previous literature. This included: resident's demographic characteristics (age, gender, LTC facility, total comorbidities); reasons for collection (change in mental status, change in behaviour, change in character of urine, fever, change in gait or fall, change in voiding pattern, flank pain, patient or family request, abnormal laboratory test result, dysuria, change in functional status, previous UTI, malaise); baseline functional capabilities (ADL score [scored out of 28], disorganized speech, altered perceptions, unresponsive episodes or lethargy in the past seven days), and nurse-reported symptoms which were listed as dichotomous variables (i.e., yes or no); these variables included fever, change in behaviour, change in mental

status, diarrhea, abdominal pain, shortness of breath, weakness, dysuria, change in character of urine, change in frequency of urination, and flank pain. Values with two or fewer positive responses were eliminated (change in functional status, change in gait or fall, result of other workup performed, other concurrent infection, dehydration, shortness of breath, syncope, diarrhea, baseline unresponsiveness, cough).

2.5 Data Analysis

Analyses were performed using SPSS Version 20.0 (IBM Corporation, USA). First, percentage of baseline characteristics were presented for categorical variables, and mean and standard deviation (SD) for continuous variables. Univariate logistic regression was first performed to determine if nurse-reported symptoms were associated with the main study outcomes. Change in functional status (ADL score) over time was analyzed using a repeated measures ANOVA comparing the three time-points (baseline, 48 hours and 5 to 7 days). Symptoms and functional status were qualitatively described over time.

A multivariable logistic regression was performed following results of the univariate regression. The factors identified from the univariate regression with a p-value less than and equal to 0.2 were included in the multiple regression to determine their association with significant growth. These variable(s) included: male sex, long-term care facility, change in voiding pattern, patient or family request, change in mental status, and change in character of urine.

Chapter 3: Results

3.1 Participant Flow

Participants were recruited as outlined in Figure 1. In total, 174 specimens were screened for inclusion, with 73 specimens excluded. One-hundred and one (101) specimens from 101 participants were included for data analysis; 63 specimens had urine culture result of non-significant growth (including those cultures with mixed-growth contamination) and 38 specimens had urine culture result of significant growth. The recruitment was stopped when the sample size was reached.

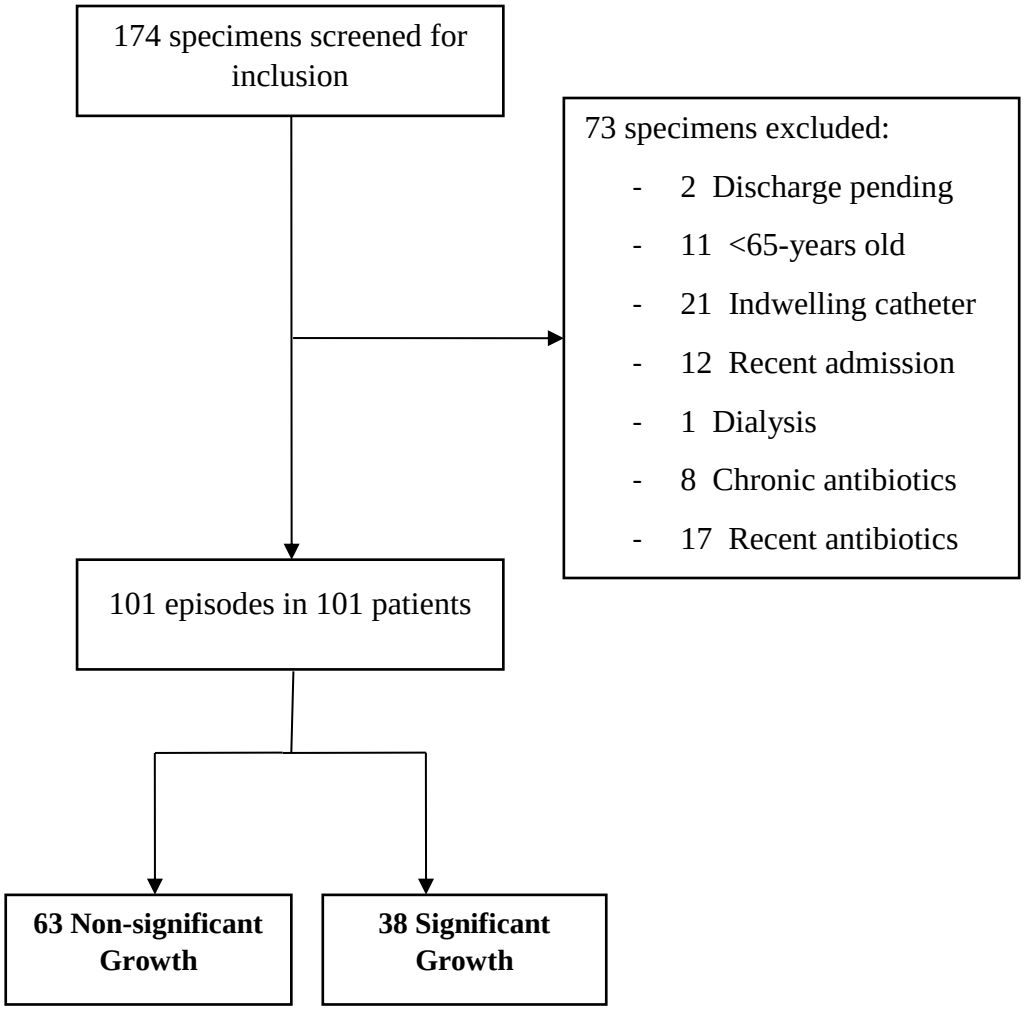

Figure 3.1: Participant Flow

3.2 Participant Demographics

The patient demographics are summarized in Table 3.1. The study population was 79.2% female, had a mean (±S.D.) age of 84.0 ± 8.6 years and had an average of 1.8 ± 1.0 comorbidities per patient, with the most common being dementia (57.4%). The baseline ADL score was 11.9 ± 8.7 (where a score of zero representing total independence and a

score of 28 representing total dependence). Nineteen (18.8%) patients experienced altered perception or lethargy, 12 (11.9%) patients experienced disorganized speech and 1 (1.0%) patient experienced unresponsiveness in the seven days prior to urine collection.

Table 3.1: Demographic characteristics

Characteristic (n=101)	Value
Age, years, mean ± SD	84.0 ± 8.6
Female sex, %	79.2
Long-term Care Facility, n (%)	
A, n (%)	26 (25.7)
B, n (%)	9 (8.9)
C, n (%)	23 (22.8)
D, n (%)	20 (19.8)
E, n (%)	15 (14.9)
F, n (%)	8 (7.9)
Number of comorbidities, mean ± SD	1.8 ± 1.0
Dementia, n (%)	58 (57.4)
Stroke, n (%)	13 (12.9)
Liver disease, n (%)	1 (1.0)
Depression, n (%)	41 (40.6)
Kidney disease n (%)	12 (11.9)
Diabetes, n (%)	25 (24.8)
Cancer, n (%)	9 (8.9)
COPD, n (%)	15 (14.9)
Baseline ADL Score, mean ± SD (Independent = 0, Total Dependence = 28)	11.9 ± 8.7
Mental status in past 7 days, n (%)	
Disorganized speech	12 (11.9)
Altered Perception	19 (18.8)
Unresponsiveness	1 (1.0)
Lethargy	19 (18.8)

3.3 Primary Outcome

Table 3.2 outlines the reasons that nurses collected urine for culture, and Table 3.3 outlines the factors correlated with significant growth (i.e., positive urine culture).

Reasons for urine collection ranged from one to seven reasons (mean 2.0 reasons). Change in behaviour (34.7%), dysuria (30.7%) and change in character of urine (29.7%) were among the most common reasons for submission. Change in mental status (25.7%) and change in voiding pattern (20.8%) were also common reasons for submission.

Male sex (OR = 5.58, [95% C.I. = 1.23, 25.43]) and change in mental status (OR = 13.83, [95% C.I. 1.8, 105.81]) were the only statistically significantly associated variables with positive urine culture in binomial regression analysis. LTCF (OR = 1.39, [95% C.I. 0.95, 2.02]), change in character of urine (OR = 14.51, [95% C.I. = 0.66, 320.71]) and baseline periods of lethargy (OR= 4.20, [95% C.I. = 0.91, 19.37]) approached significance.

A final multiple logistic regression was performed using predictors identified from the univariate logistic analysis with a p-value = 0.2; the factors included in the model were gender (male sex), LTCF, change in voiding pattern, patient or family request, change in mental status and change in character of urine. Table 3.4 illustrates these results. The model was not statistically significant ($\chi^2_{(39)} = 39.16$, p-value = 0.463) and only explained 10.3% of the variance in factors associated with significant growth. While not significant, LTCF, and family request for urine culture, were 1.9 (OR = 1.86, [95% C.I. = 0.341, 10.226]) and 2.4 (OR = 2.37, [95% C.I. = 0.456, 12.40]) times more likely to have a significant growth culture result, respectively.

Table 3.2: Reasons for urine culture collection (n = 101)

Clinical Reason	n	% (N=101)
Change in behaviour	35	34.7
Dysuria	31	30.7
Change in character of urine	30	29.7
Change in mental status	26	25.7
Change in voiding pattern	21	20.8
Other reason	14	13.9
Patient or family request	11	10.9
Previous UTI	11	10.9

Table 3.3: Binary logistic regression of predictors with significant growth (n = 38 of 101 episodes)

Demographics	OR	95% C.I.	p-Value
Age	0.99	0.93-1.06	0.79
Male Sex	5.58	1.23-25.43	0.026
Total Comorbidities	0.87	0.53-1.47	0.61
LTC Facility	1.39	0.95-2.02	0.087
Stated Reason for Urine Collection			
Fever	0.00		1.0
Change in voiding pattern	16.70	**0.16-1754.36**	0.24
Patient or family request	0.12	0.007-1.91	0.13
Abnormal laboratory test result	2.85	**0.16-51.27**	0.48
Previous UTI	1.28	**0.19-8.48**	0.80
Baseline Functional Capacity			
Baseline ADL Score	1.03	0.97-1.10	0.38
Baseline Disorganized Speech	1.02	0.14-7.59	0.97
Baseline Altered Perception	0.36	0.05-2.60	0.31
Baseline Periods of Lethargy	4.20	0.91-19.37	0.065
New Symptoms			
Change in Behaviour	3.41	0.11-104.90	0.48
Change in Mental Status	13.83	1.81-105.81	0.011
Abdominal Pain	0.68	0.083-5.60	0.72
Weakness	0.90	0.026-30.91	0.95
Worsening in ADL Score	0.00		1.0
Dysuria	2.10	0.14-32.13	0.60
Change in Character of Urine	14.51	0.66-320.71	0.090
Flank Pain	infinity		1.0

Change in Frequency of Urination	0.079	0.002-2.62	0.16

Table 3.4: Multiple logistic regression model of predictors with significant growth culture results

Variable	Odds Ratio	95% C.I.	p-value
Male Sex	0.48	0.16, 1.45	0.19
Long-term care facility	1.87	0.34, 10.23	0.47
Change in voiding pattern	1.07	0.37, 3.12	0.90
Patient or family request	2.38	0.46, 12.40	0.30
Change in mental status	1.09	0.38, 3.15	0.87
Change in character of urine	1.07	0.41, 2.80	0.89

A repeated measures ANOVA with a Greenhouse-Geisser correction determined that mean ADL score was not statistically significantly different between time points ($F(1.070, 102.714) = 0.891$, $P = 0.350$). The primary outcome of clinical response to therapy is presented in Table 3.5. Using a two-sided paired t-test, the patient's ADL score at baseline (prior to clinical decline which prompted the urine collection) was compared to their ADL score at 48-hours (the time at which culture results are available to the physician), and their ADL score at five to seven days (when resolution of episode should occur), in groups based on their culture result and treatment decision. There was no significant difference observed in functionality in any combination of groups (i.e., baseline to 48-hours or between 48-hours and 5-7 days).

Table 3.5: Changes in activities of daily living (ADL) score*

Group	N	Mean ADL Baseline	Mean ADL 48 Hours	p value Baseline to 48 Hours	Mean ADL 5-7 days	p value 48 Hours to 5-7 Days
Culture positive, treated	28	11.5	12.2	0.30	12.2	1.00
Culture positive, not treated	9	17.6	16.4	0.35	16.4	1.00
Culture negative, treated	18	12.1	12.1	1.00	12.1	1.00
Culture negative, not treated	44	10.9	11.2	0.29	11.3	0.34

***** Zero represents total independence, 28 represents total dependence

3.4 Secondary Outcomes

The secondary outcome of the physician's decision to treat given culture results is presented in Table 3.6. Antibiotics were prescribed in 48 of 101 episodes (47.5%); of those treated, 25 (24.8%) were prescribed nitrofurantoin and 14 (13.9%) were prescribed TMP/SMX. Agreement between treatment decision and significant growth was fair (κ = 0.44) but antibiotics were incorrectly prescribed to patients with nonsignificant growth in 19/48 (40%) of prescriptions. Nine (17.0%) of 53 patients who had a culture result of significant growth were not prescribed antibiotics. Of the 101 specimens included, 32 (31.2%) were considered inappropriate (Table 3.6) using urine culture result as the reference standard; it should be noted that the culture result alone does not distinguish between UTI and ASB. Treatment duration lasted for a mean of 7.6 ± 2.5 days with a range of 1 day to 15 days. The time between urine submission and start of treatment was an average of 1.44 ± 2.9 days with a range of treatment given eight days prior to collection for the presumed UTI and ten days following collection for the same.

Of the 38 urine specimens collected with significant growth, 25 (65.8%) grew *Escherichia coli*, five (13.2%) grew *Proteus* species, four (10.5%) grew *Klebsiella* species, three (7.9%) grew *Enterococcus* species and one (2.6%) grew yeast.

Table 3.6: Treatment decision

	Treatment Decision		
Growth	**Antibiotic Prescribed**	**Antibiotic Not Prescribed**	**Total**
Significant Growth	29 (60)	9 (17)*	38
Non-significant Growth	19 (40)*	44 (83)	63
Total	48	53	101

* Inappropriate treatment decision. Data presented as n or n (%)

A binary logistic regression showed that a resident's age, gender, LTC facility, number of total comorbidities and baseline ADL were not associated with the decision to treat (Table 3.7) . In 21 (43.8%) of 48 treated cases, treatment was given before preliminary culture results were available. Among those patients with a positive culture who were treated, four (13.7%) of the 29 patients were given an antibiotic to which the isolated bacteria were reported as resistant.

Table 3.7 Binary logistic regression of predictors of treatment decision

Variable	**Odds Ratio**	**95% C.I.**	**p-value**
Age	0.974	0.927, 1.023	0.295
Male Sex	0.626	0.230, 1.704	0.626
Total Comorbidities	0.725	0.725, 0.480	0.725
Baseline ADL	0.992	0.947, 1.040	0.992

The secondary outcome of whether the physician was following published guidelines for diagnosing UTI in the long-term care population without an indwelling catheter was examined. These guidelines may include vital signs and blood counts, but most observed episodes did not have a record of vital signs or blood testing so it was concluded that physicians and/or nursing staff were not following guidelines. Body temperature was measured for eight (7.9%) episodes, blood pressure was measured for six (5.9%) episodes, a dipstick was performed for 25 (24.8%) episodes and a complete blood count was obtained for 16 (15.8%) episodes.

Chapter 4: Discussion

4.1 Findings and Implications

This study found that most of the reasons why nurses chose to collect a specimen were not associated with a positive culture result. Male sex and change in mental status were the only two significant predictors of significant growth (i.e., positive urine culture) in our binary logistic regression analysis.

The finding that gender contributed to the predictive value of urine culture may have been attributed to males providing a cleaner urine collection than females (females were twice as likely to have a culture result of "mixed growth contamination" than males – 15 (18.8%) versus 2 (9.5%), respectively). A change in baseline mental status was a predictor of significant growth in the binary logistic regression. This loss significance in the multivariate logistic regression. Twenty-two (57.9%) residents with a positive urine culture result were reported to have dementia, compared to 37 (58.7%) without a positive urine culture result, suggesting that dementia alone may explain the association between the change in mental status and positive urine culture. Residents with cognitive impairment or decline are more likely to have a positive urine culture (19). Our data cannot provide the specific etiology for a change in mental status, so the correlation between change in mental status and positive urine culture may be due to another confounding fact.

Our study also found that culture results did not appear to influence a physician's decision to treat a suspected UTI, since physicians chose to treat residents with culture-

negative results (40% of recorded episodes) and chose not to treat those with culture-positive results (17% of recorded episodes). Physicians also treated residents prior to culture results becoming available, and sometimes prescribed antibiotics to which the organisms were resistant. This observation may be explained by several factors. Nurses in the LTC setting have a major influence on whether a physician prescribes an antibiotic. They often are more familiar with residents and would notice subtler changes in their clinical status than a physician and often advocate treatment on their behalf. Furthermore, individual prescribing behaviour of physicians may play an important role. For example, an on-call physician not familiar with a LTC facility may prescribe an antibiotic without performing an assessment, to act conservatively to prevent further complications. Pressure from family members is a factor to consider as well. Often a family member will feel that something is "off" about their loved one and request a urine culture to be submitted and subsequently, request an antibiotic (27).

Prescribing behaviour in response to positive (or negative) culture results could be addressed through education of both physicians and nurses including development of treatment algorithms and continuing audit and feedback (35), but this is resource intensive and behaviour changes are rarely sustained. Other forms of intervention like changes in urine culture reporting can have a significant influence on prescribing behaviour; a recent study performed in the acute care setting saw an absolute risk reduction of 36% (C.I. = 15%-57%, $p = 0.002$) for treatment of ASB among non-catheterized inpatients (36) by simply restricting reporting of urine culture results, and requesting the physician to call the laboratory to release sensitivity results. But if

physicians chose to treat without obtaining culture results, then this intervention would not be effective.

Similarly, the current study attempted to evaluate whether physicians were following published clinical guidelines. The intention was to capture whether criteria were being followed at the time of the nurse (or delegate) interview (refer to Appendix 3). Many of the LTC facilities only recorded vital signs on a quarterly basis, and in some instances, less frequently, as some residents are difficult and uncooperative. Vital signs were accessed through the LTC EHR system, and therefore any vital signs not accessible to our analysis. Because vital signs were not collected or available, we could not evaluate adherence to treatment guidelines which require changes in vital signs for UTI diagnosis.

Many providers may be unaware of current published guidelines (37), and these guidelines may not address residents who present with only non-localizing symptoms (5). Likewise, these guidelines are difficult to apply to residents with advanced dementia who are non-verbal and cannot reliably express any symptoms they may be experiencing (38). For example, over half (57.4%) of the residents assessed in the present study were listed as having dementia, so it is reasonable to assume that they represent a large proportion of LTCF populations for which the minimum criteria guidelines would be hard to apply. There is also evidence to suggest that even if prescribers adhered to the published guidelines, that it would not be associated with lower rates of antibiotic prescribing but rather a higher rate of inappropriate antibiotic prescribing (39). Thus, it seems that there is a need for updated, evidence-based guidelines.

In the present study, we also aimed to assess the clinical response to antimicrobial therapy by measuring change in functionality using the ADL score. We observed no functional improvement associated with antibiotic treatment (Table 5). ADL scores did not change significantly during the seven-day follow-up period, even when stratified by treatment and culture result; this suggests that antibiotic therapy did not have clinical benefit. This calculation, however, is based on mean change in ADL; it is possible that individuals did benefit with treatment over the study period but not so that it was detectable. Of the residents assessed, only 7 out of 101 (6.9%) demonstrated individual improvement and/or decline in ADL over the study period. Response bias may have influenced in the lack of ADL improvement observed, because if the same nurse (or delegate) completed the scale each time, they may have given the same answer without much reflection. Which nurses were interviewed during the study period was not recorded, therefore this bias cannot be excluded.

The study population at baseline had moderate functional impairment (ADL Score 11.9 ± 8.7) which may explain why we did not see any improvement with therapy compared to a population with mild or no functional impairment. For example, if a resident who previously was able to ambulate but experienced a functional change whereby they couldn't ambulate well anymore – treatment would appear to benefit them more so than a resident who is always non-ambulatory. Additionally, the follow-up period may not have been long enough to detect a further functional decline. Without a randomized design, culture-positive and culture-negative residents may have differed at baseline leading to a biased observation.

We observed a culture positivity rate among those residents with urine collected to be similar to that of the published rate of ASB for the LTC population (38% versus 40%, respectively)(5, 15). This is consistent with previous studies (40) suggesting that clinical suspicion of UTI is not contributory without further investigation of any signs and symptoms.

Published clinical criteria for UTI do not have high accuracy. When compared against laboratory evidence of UTI, the positive-predictive value of the published diagnostic criteria ranged from 52%-57% (6, 16). It may be more useful to consider using a urine dipstick test to exclude the possibility of UTI, as a negative dipstick for leukocyte esterase and nitrite has been known to have a 100% negative-predictive value (12).

4.2 Limitations

Our study had several limitations, with the main limitation being a small sample size. A sample size calculation was not performed; thus, we may have been underpowered to detect a significant predictor. Typically, a guide of ten events per predictor tested would be needed to achieve a sufficient sample size; in this study, an event would be a positive culture meaning that we would require a minimum of 100 positive urine culture results. The inadequate sample size is reflected in our wide confidence intervals.

The second limitation was that we only considered input from LTCF nurses (or delegates). Physicians, other caregivers or family were not consulted or interviewed

regarding the signs and symptoms of UTI, and they may have had differing perceptions. Nurses, however, in the LTC setting are very influential with regards to a resident's care; they would relay any clinical change to the physician. In many instances, we were not able to interview the nurse who collected the urine specimen due to changes in shifts; the nurse on the next shift may not have yet known the reasons for urine collection. Finally, measuring ADL score as a response to therapy may not have captured other significant evidence of clinical improvement. The reliability of this scale over short intervals of time is not known and this may have contributed to our lack of functional improvement seen; typically, ADL is assessed every 90 days in LTC. A different scale measuring health outcomes may have been useful in this study as physicians may be more inclined to treat residents who are experiencing a decline in their perceived quality of life due to any signs and symptoms of UTI they may be experiencing; this could explain why some residents received treatment even though they were culture negative.

4.3 Future Studies

The present study was the first to observe clinical outcomes (ADL score) as a measure of effectiveness of diagnosis and treatment for UTI in the LTCF setting. Future studies should evaluate diagnostic criteria for UTI based on clinical benefit following successful treatment instead of based on culture. Additionally, future studies should explore methods to reliably separate ASB from UTI among LTC residents with severe cognitive impairment. Kjölvmark *et al*. produced a study reporting moderate accuracy using specific urinary biomarkers (41). This type of diagnostic test would be useful in

further studies to see which biomarkers predict improvement in clinical status in response to treatment of bacteriuria.

There is also adequate equipoise to suggest a prospective, randomized clinical trial comparing early to delayed antibiotic treatment, or comparing antibiotic treatment with rehydration (19).

Lastly, a final suggestion for future studies would be to implement a delirium protocol for diagnosis of UTI in LTC and preform a pre- and post-intervention analysis. This type of protocol is used in both acute and intensive care settings. In this protocol, functional decline or other decompensation experienced by LTC residents would be investigated in a flow-chart type manner to ultimately reduce the number of urine cultures performed and the number of antibiotics prescribed. For the febrile resident without localizing symptoms, blood cultures would be collected since a diagnosis of UTI can be made if a blood culture isolate is the same as the organism isolated from the urine, given there is no alternative site of infection (9). In the afebrile resident, hydration would be encouraged to rule out dehydration as a source of clinical decline. If deterioration persists, further investigation would be warranted including a physical exam and blood count. If a resident has localizing urinary symptoms, a urine culture may be collected using an in/out catheter and a urine dipstick test should be performed. Treatment for UTI would be considered only for those with a positive dipstick result for leukocyte esterase and a positive urine culture. Finally, this protocol, when evaluated, could be audited to ensure compliance and impact on antibiotic prescription rate.

Chapter 5: Conclusions

While not adequately powered to determine a significant association, our study is able to conclude that diagnosis of UTI in LTCF is still not well defined and that the perceived symptoms of UTI are not predictive of significant growth. This suggests that symptoms alone cannot define UTI and that further investigation is warranted to determine the source of decompensation in LTC residents. Our study also saw that there is much to be improved in the way antibiotics are prescribed in LTC; many physicians were inappropriate in their treatment decision and in certain cases, chose not to treat at all. Further investigation is also needed to develop a well-defined, reliable diagnostic criterion for UTI in LTC that is mindful of the high prevalence of ASB.

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Appendix

Appendix 1: Study Information Sheet

Letter of Information Regarding Research Study

TITLE: Pilot Prospective Observational Study of Diagnosis of Urinary Tract Infection (UTI) in Long Term Care (LTC)

INVESTIGATOR(S): Peter Daley MD, Aaron McKim MD, Natalie Bridger MD, Glenda Compton RN, Judy O'Keefe RN, Susan Wakeham BSc

You have been invited to take part in a research study. Taking part in this study is voluntary. It is up to you to decide whether to be in the study or not. You can decide not to take part in the study. If you chose not to take part, please say "No" to the research staff. If you decide to take part, you are free to leave at any time.

The study has been reviewed by the Health Research Ethics Authority and granted approval.

Before you decide, you need to understand what the study is for, what risks you might take and what benefits you might receive. This information sheet explains the study. A researcher will discuss the study with you and provide a copy of this information letter to you before you decide to participate. Your verbal consent will be requested before any information is collected.

Please read this carefully. Take as much time as you like. If you like, take it home to think about for a while. Mark anything you do not understand, or want explained better. After you have read it, please ask questions about anything that is not clear.

The researchers will:

- discuss the study with you

- answer your questions
- keep confidential any information which could identify you personally
- be available during the study to deal with problems and answer questions

1. Introduction/Background:

The diagnosis of urinary tract infection (UTI) in long term care facilities (LTC) is difficult, since many residents have positive urine culture at all times. The researchers are looking at why nursing staff decide to collect urine for culture from residents. Also, are the same symptoms present during antibiotic treatment for UTI?

2. Purpose of study:

Since antibiotic treatment is often given inappropriately, the researchers are interested in improving the diagnosis and treatment of UTI in LTC.

3. Description of the study procedures:

Nursing staff familiar with a resident will be approached by a research team member if a urine sample has been collected for culture. The research team member will inquire about the resident's baseline level of function and what change in functional status has been observed. The nursing staff is requested to provide verbal answers to questions to complete the case report form. The research team member will consider laboratory results and antibiotic treatment decisions. The same assessment will be performed after 2 days and again after 7 days from the day of urine collection. The study will not influence decision making by nursing staff.

4. Length of time:

The study will collect information from 100 LTC residents with suspected UTI. This is expected to take 1-2 months during the summer of 2013. Each interview of nursing staff to collect the relevant information will take less than ten minutes.

5. Possible risks and discomforts:

The study is considering decision making by nursing staff. Staff members will not be identified by name and no feedback about individual decision making will be provided to nursing staff. Discomfort to nursing staff will include time required to answer questions about resident status information.

6. Benefits:

It is not known whether this study will benefit residents. If we find useful information about diagnosis of UTI in LTC, it could lead to change in policy regarding collection and interpretation of urine culture information. The study will not directly benefit nursing staff.

7. Liability statement:

This information sheet is designed to explain the study to nursing staff and ensure that nursing staff understand fully. If you choose to participate, you do not give up your legal rights. Researchers or agencies involved in this research study still have their legal and professional responsibilities.

8. What about my privacy and confidentiality?

Protecting your privacy is an important part of this study. Every effort to protect your privacy will be made. However it cannot be guaranteed. For example we may be required by law to allow access to research records.

When you provide verbal consent for participation you give us permission to:

- Collect resident status information from you, without identifying you by name
- Share information with the people conducting the study
- Share information with the people responsible for protecting your safety

Access to records

The members of the research team will see study records that identify the facility by name.

Other people may need to look at study records that identify the facility by name. This might include the research ethics board. You may ask to see the list of these people. They can look at study records only when supervised by a member of the research team.

Use of your study information

The research team will collect and use only the information they need for this research study. This information will include:

- Reasons that nursing staff decide that a resident may have UTI
- Resident demographic and clinical information but not resident identification, including activities of daily living, mental status, vital signs and symptoms
- Urine culture results
- Antibiotic treatment decisions
- Resident clinical status after urine culture collection, at day 2 and day 7

Your facility name and contact information will be kept secure by the research team in Newfoundland and Labrador. It will not be shared with others without your permission. Your name will not appear in any report or article published as a result of this study. Information collected for this study will kept for five years.

If you decide to withdraw from the study, the information collected up to that time will continue to be used by the research team. It may not be removed. This information will only be used for the purposes of this study. Information collected and used by the research team will be stored at the office of Peter Daley at the Health Sciences Center. Dr. Daley is the person responsible for keeping it secure.

Your access to records
You may ask the researcher to see the information that has been collected about your facility.

9. Questions or problems:

If you have any questions about taking part in this study, you can meet with the investigator who is in charge of the study at this institution. That person is:

Peter Daley MD, principal investigator.

Room 1J421, 300 Prince Phillip Dr. A1B 3V6

709-777-2089 or 709-777-7801 (Meaghan Lethbridge)

Or you can talk to someone who is not involved with the study at all, but can advise you on your rights as a participant in a research study. This person can be reached through:

Ethics Office

Health Research Ethics Authority
709-777-6974 or by email at info@hrea.ca

10. Declaration of financial interest, if applicable

There is no financial support or external budget to conduct the study.

Copies will be made available to each staff member at a participating facility, and posted at each nursing unit, in order to inform staff about the study details.

Appendix 2: Health Research Ethics Authority approval

Ethics Office
Suite 200, Eastern Trust Building
95 Bonaventure
Avenue St.
John's, NL
A1B 2X5

June 21, 2013

Dr. Peter Daley
Health Science Centre
300 Prince Philip Drive
St. John's, NL

Dear Dr. Daley

Reference #13.127

RE: **Pilot Prospective, Observational Study of Diagnosis of Urinary Tract Infection (UTI) in Long**
Term Care (LTC)

This will acknowledge receipt of your correspondence.

This correspondence has been reviewed by the Chair under the direction of the Board. ***Full board approval*** of this research study is granted for one year effective **June 13, 2013.**

This is to confirm that the Health Research Ethics Board reviewed and approved or acknowledged the following documents (as indicated):

- Application, approved
- Letter of information, dated June 19, 2013 version 2, approved

- Letter to Medical Records, acknowledged

MARK THE DATE

This approval will lapse on **June 12, 2014**. It is your responsibility to ensure that the Ethics Renewal form is forwarded to the HREB office prior to the renewal date. *The information provided in this form must be **current to the time of submission** and submitted to HREB **not less than 30 nor more than 45 days** of the anniversary of your approval date.* The Ethics Renewal form can be downloaded from the HREB website http://www.hrea.ca.

The Health Research Ethics Board advises THAT IF YOU DO NOT return the completed Ethics Renewal form prior to date of renewal:

- *Your ethics approval will lapse*
- *You will be required to stop research activity immediately*
- *You may not be permitted to restart the study until you reapply for and receive approval to undertake the study again*

Lapse in ethics approval may result in interruption or termination of funding

It is **your responsibility to seek the necessary approval from the Regional Health Authority or other organization as appropriate.**

Modifications of the protocol/consent are not permitted without prior approval from the Health Research Ethics Board. Implementing changes in the protocol/consent without HREB approval may result in the approval of your research study being revoked, necessitating cessation of all related research activity. Request for modification to the protocol/consent must be outlined on an amendment form (available on the HREB website) and submitted to the HREB for review.

This research ethics board (the HREB) has reviewed and approved the research protocol and documentation as noted above for the study which is to be conducted by you as the qualified investigator named above at the specified site. This approval and the views of this Research Ethics Board have been documented in writing. In addition, please be advised that the Health Research
Ethics Board currently operates according to *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*; *ICH Guidance E6: Good Clinical Practice* and applicable laws and regulations. The membership of this research ethics board is constituted in compliance with the membership requirements for research ethics boards as defined by *Health Canada Food and Drug Regulations Division 5; Part C.*

Notwithstanding the approval of the HREB, the primary responsibility for the ethical conduct of the investigation remains with you.

We wish you every success with your study.

Sincerely,

Dr. Fern Brunger
Chair, Non-Clinical Trials
Health Research Ethics Board

C C VP Research c/o Office of Research, MUN
VP Research c/o Patient Research Centre, Eastern Health
HREB meeting date: June 27, 2013

Appendix 3: Case Report Form

UTI in LTC Case Report Form
Researcher to complete, based on interview of nursing staff

SECTION 1: Demographics			
Study Number (1-100)	**Date of Birth**	**LTC Home:**	**Gender**
	_____/_____/_____ Day Month Year	☐ Hoyles Escasoni (1) ☐ Agnes Pratt (5) ☐ Masonic Park (2) ☐ St. Lukes's (6) ☐ GlenBrook Lodge (3) ☐ St. Patrick's (4)	☐ Female (0) ☐ Male (1)

SECTION 2: Exclusion Criteria (**Please tick the following that apply): (If excluded from study, no further data collected)**

☐ Not anticipated to remain in the Nursing home for long-term care (1)

☐ Terminal (anticipated life expectancy <4 weeks) (2)

☐ Younger than 65 years (3)

☐ Indwelling catheter (4)

☐ Resided in the nursing home for less than 4 weeks (5)

☐ Undergoing dialysis (6)

☐ Undergoing chronic suppressive antibiotic therapy for recurrent UTI (7)

☐ Completed a course of antibiotics within the last 7 days for any reason (8)

SECTION 3: Inclusion Criteria			
Date of Urine Submission	**Reason For Suspected UTI (Please tick all of the following that apply):**		
_____/_____/_____ Day Month Year	☐ Change in mental status (1)	☐ Flank pain (7)	☐ Other infection (13)
	☐ Change in behavior (2)	☐ Other workup (8)	☐ Change in functional status (14)
Date of Interview of Nursing Staff			

_____/_____/_____ Day Month Year Was the nurse who suspected UTI (collected urine) interviewed? ☐ Yes (1) ☐ No, someone else (0)	☐ Change in character of urine (3)	☐ Patient or family request (9)	☐ Previous UTI (15)
	☐ Fever or chills (4)	☐ Abnormal laboratory test result (10)	☐ Malaise (16)
	☐ Change in gait or fall (5)	☐ Syncope (11)	☐ Dehydration (17)
	☐ Change in voiding pattern (6)	☐ Dysuria (12)	
	☐ Other(18): Describe: _____		

SECTION 4: Baseline Assessment

Comorbidities (yes/no):

_____ Dementia (1) _____ Depression (4) _____ Cancer (7)

_____ Stroke (2) _____ Kidney Disease (5) _____ Chronic Obstructive Pulmonary Disease (8)

_____ Liver Disease (3) _____ Diabetes (6) _____ Congestive Heart Failure (9)

ADL:	Independent (0 Points)	Light Assist (1 Point)	Moderate Assist (2 Points)	Heavy Assist (3 Points)	Total Dependence (4 Points)
Bed Mobility					
Transfer					
Locomotion within facility					
Dressing					
Toilet Use					
Personal Hygiene					
Eating					
Total Score:	**_____/28**				

Mental Status (present/absent in the last 7 days):	**Last recorded Vital Signs DD/MM/YYYY ___/___/_____**
_____ Episodes of Disorganized Speech _____ Unresponsive	Temperature: _____°C Heart Rate: _____ BPM
_____ Periods of Altered Perception _____ Periods of Lethargy	Blood Pressure: _____/_____ O_2 Saturation: _____%
Total Score: _____/ 4	

SECTION 5: New Symptoms as Perceived by Patient or Attendant

Constitutional

☐ Fever (1) ☐ Cough (4) ☐ Shortness of Breath (7)

☐ Behavior Change (2) ☐ Diarrhea (5) ☐ Weakness or Fatigue (8)

☐ Mental Status Change (3) ☐ Abdominal Pain (6) ☐ Functional Decline (New ADL Score: _____/28) (9)
- ☐ Acute Onset ☐ Fluctuating Course
- ☐ Inattention ☐ Disorganized Thinking or Decreased Consciousness

Genitourinary	**Vital Signs (if recorded as part of routine care) DD/MM/YYYY ___/___/_____**
☐ Dysuria (1) ☐ Change in Frequency of Urination (3)	Temperature: _____°C Heart Rate: _____ BPM
☐ Change in Character of Urine (2) ☐ Flank Pain (4)	Blood Pressure: _____/_____ O_2 Saturation: _____%

SECTION 6: Lab Data if Collected

Method of Collection	**Dipstick Results**	**Urinalysis Results**

☐ Clean Catch (1) ☐ In/Out Catheter (2) ☐ Other (3): _____	Glucose _____ Protein _____ Blood_____ Bilirubin _____ Casts _____ Ketones _____ Nitrite _____ PH _____ Leukocyte _____ Specific Gravity _____ Urobilinogen _____	RBC _____/HPF WBC _____/HPF Epithelials _____/HPF Other _____/HPF
WBC Count and Differential	**Culture Results**	
WBC_____ X 10^9/L Bands _____x 10^9/L _____%	☐ Contamination (1) ☐ No Growth (0) ☐ Growth (2): Count _____ X 10^6 CFU/L Identification: _____	

Second Urine Culture Submission **Collection Date** ___/___/____ **DD/MM/YYYY**

Method of Collection	**Dipstick Results**	**Urinalysis Results**
☐ Clean Catch (1) ☐ In/Out Catheter (2) ☐ Other (3): _____	Glucose _____ Protein _____ Blood_____ Bilirubin _____ Casts _____ Ketones _____ Nitrite _____ PH _____ Leukocyte _____ Specific Gravity _____ Urobilinogen _____	RBC _____/HPF WBC _____/HPF Epithelials _____/HPF Other _____/HPF
Culture Results		

☐ Contamination(1)
☐ No Growth (0)
☐ Growth(2): Count _____ X 10^6 CFU/L
Identification: _____

Third Urine Culture Submission		**Collection Date** ___/___/____ **DD/MM/YYYY**
Method of Collection	**Dipstick Results**	**Urinalysis Results**
☐ Clean Catch (1) ☐ In/Out Catheter (2) ☐ Other (3): _____	Glucose _____ Protein _____ Blood_____ Bilirubin _____ Casts _____ Ketones _____ Nitrite _____ PH _____ Leukocyte _____ Specific Gravity _____ Urobilinogen _____	RBC _____/HPF WBC _____/HPF Epithelials _____/HPF Other _____/HPF

Culture Results

☐ Contamination (1)
☐ No Growth (0)
☐ Growth (2): Count _____ X 10^6 CFU/L
Identification: _____

SECTION 7: Treatment Decision			
Drug	**Dose**	**Route and Frequency**	**Duration**
			___/___/____ ___/___/____ **DD/MM/YYYY until DD/MM/YYYY**

SECTION 8: McGeer Criteria (Circle answer):	
Fever: Single oral temperature >37.8°C **YES/NO/NOT COLLECTED** (1/0/2) Repeated oral temperatures >37.2°C or rectal temperatures >37.5°C **YES/NO/NOT COLLECTED** (1/0/2)	**Leukocytosis:** Neutrophilia (>14,000 leukocytes/mm^3) **YES/NO/NOT COLLECTED** (1/0//2) Left shift (>6% bands or ≥1,500 bands/mm^3) **YES/NO/NOT COLLECTED** (1/0/2)
Acute Change in Mental Status: Acute onset **YES/NO** (1/0) Fluctuating Course **YES/NO** (1/0) Inattention **YES/NO** (1/0) Either disorganized thinking or altered level of consciousness **YES/NO** (1/0)	**Acute Functional Decline:** New 3-point increase in total activities of daily living (ADL) Score **YES/NO** (1/0)

For Residents without an Indwelling Catheter (Both Criteria 1 and 2 must be present):

1. At least one of the following sign or symptom subcriteria:

    a) Acute dysuria or acute pain, swelling, or tenderness of the testes, epididymis, or prostate **YES/NO** (1/0)

    b) Fever or leukocytosis and at least one of the following localizing urinary tract subcriteria

        i. Acute costovertebral angle pain or tenderness **YES/NO** (1/0)
        ii. Suprapubic pain **YES/NO** (1/0)
        iii. Gross hematuria **YES/NO** (1/0)
        iv. New or marked increase in incontinence **YES/NO** (1/0)
        v. New or marked increase in urgency **YES/NO** (1/0)
        vi. New or marked increase in frequency **YES/NO** (1/0)

    c) In the absence of fever or leukocytosis, then two or more of the following localizing urinary tract subcriteria

        i. Suprapubic pain **YES/NO** (1/0)
        ii. Gross hematuria **YES/NO** (1/0)
        iii. New or marked increase in incontinence **YES/NO** (1/0)
        iv. New or marked increase in urgency **YES/NO** (1/0)
        v. New or marked increase in frequency **YES/NO** (1/0)

2. One of the following microbiologic subcriteria

    a) At least 10^5 cfu/mL of no more than 2 species of microorganisms in a voided urine sample **YES/NO** (1/0)

    b) At least 10^2 cfu/mL of any number of organisms in a specimen collected by in-and-out catheter **YES/NO** (1/0)

SECTION 9: Reassessment of Symptoms 48 Hours after UTI Suspected performed DD/MM/YYYY ___/____/_____

Constitutional

☐ Fever (1) ☐ Cough (4) ☐ Shortness of Breath (7)

☐ Behavior Change (2) ☐ Diarrhea (5) ☐ Weakness or Fatigue (8)

☐ Mental Status Change (3) ☐ Abdominal Pain (6) ☐ Functional Decline (9)
☐ Acute Onset ☐ Fluctuating Course
☐ Inattention ☐ Disorganized Thinking or Decreased Consciousness

Genitourinary

☐ Dysuria (1) ☐ Change in Frequency of Urination (2) ☐ Change in Character of Urine (3) ☐ Flank Pain (4)

ADL:	Independent (0 Points)	Light Assist (1 Point)	Moderate Assist (2 Points)	Heavy Assist (3 Points)	Total Dependence (4 Points)
Bed Mobility					
Transfer					
Locomotion within facility					
Dressing					
Toilet Use					
Personal Hygiene					
Eating					
Total Score:	**_____/ 28**				

Mental Status (present/absent):	**Vital Signs (if recorded as part of routine care) DD/MM/YYYY __/___/_____**
_____ Episodes of Disorganized Speech _____ Unresponsive	Temperature: _____°C Heart Rate: _____ BPM

_____ Periods of Altered Perception _____ Periods of Lethargy **Total Score: _____/ 4**	Blood Pressure: _____/_____ O_2 Saturation: _____%

SECTION 10: Reassessment of Symptoms 5-7 days after UTI Suspected performed DD/MM/YYYY ___/____/_____

Constitutional

☐ Fever (1) ☐ Cough (4) ☐ Shortness of Breath (7)

☐ Behavior Change (2) ☐ Diarrhea (5) ☐ Weakness or Fatigue (8)

☐ Mental Status Change (3) ☐ Abdominal Pain (6) ☐ Functional Decline (9)
☐ Acute Onset ☐ Fluctuating Course
☐ Inattention ☐ Disorganized Thinking or Decreased Consciousness

Genitourinary

☐ Dysuria (1) ☐ Change in Frequency of Urination (2) ☐ Change in Character of Urine (3) ☐ Flank Pain (4)

ADL:	Independent (0 Points)	Light Assist (1 Point)	Moderate Assist (2 Points)	Heavy Assist (3 Points)	Total Dependence (4 Points)
Bed Mobility					
Transfer					
Locomotion within facility					
Dressing					
Toilet Use					
Personal Hygiene					
Eating					

Total Score:	**_____/ 28**

Mental Status (present/absent):	**Vital Signs (if recorded as part of routine care) DD/MM/YYYY __/___/_____**
_____ Episodes of Disorganized Speech _____ Unresponsive _____ Periods of Altered Perception _____ Periods of Lethargy **Total Score: _____/ 4**	Temperature: _____°C Heart Rate: _____ BPM Blood Pressure: _____/_____ O_2 Saturation: _____%